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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,384	08/19/2003	Kenneth Brasel	2836-H	4836

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,384	BRASEL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 02/07/2007, has been entered.
Claims 1-3, 8-11 and 15-17 have been amended.

Claims 1-23 are pending.

Applicant's election of the species bacteria in the Response to Election of Species Requirement, filed 7/19/06, has been acknowledged.

As indicated previously, upon further consideration and search, the species has been extended to both bacterial and viral for examination purposes to advance prosecution.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

This Action will be in response to applicant's arguments, filed 02/07/2007.

The rejections of record can be found in previous Office Action, mailed 10/06/2006.

3. Priority.

Applicant's arguments in conjunction with the amended claims, filed 02/07/2007, have been fully considered but have not been found convincing with respect to the priority of the instant claims.

Applicant asserts that the instant and priority applications disclose the situation where the antigen, such as a bacterial or viral antigen, may already exist with the patient and that the Flt3-ligand may be administered as a vaccine adjuvant to enhance an immune response to the viral or bacterial antigens.

In turn, applicant submits that that it is clear that the instant specification and priority application disclose treatment of infection as the presence of the bacterial or viral antigen in the patient would arise as a result of the patient being infected with the bacteria or virus.

Although the paper copy of the USSN 09/444,027 application was not available to the examiner at this time, a scanned copy of the original filing of the application is available to the examiner via eDAN.

While original claim 3 of the USSN 09/444,027 may recite:

"A method according to claim 1 wherein the patient has an infectious disease";

it appears that this recitation of "infectious disease" relies upon the disclosure of the following on page 14, paragraph 1 of USSN 09/444,027.

"More specifically, the invention provides for the use of an effective amount of flt3-1igand to increase or mobilize dendritic cells in vivo, for example, in the patient's peripheral blood or spleen. By increasing the quantity of the patient's dendritic cells, such cells may themselves be used to present antigen to T cells. For example, the antigen may be one that already exists within the patient, such as a tumor antigen, or a bacterial or viral antigen. Flt3-L may be used, therefore, to boost the patient's lymphocyte-mediated (e.g., T cell and B cell mediated) or myeloid-mediated immune response to the already present antigens thus potentially enabling a more effective antigen-presentation to the patient's T cells."
See page 14, paragraph 1 of USSN 09/444,027.

In contrast to the reliance upon viral and bacterial infections to support the genus of "infectious diseases",
an infectious disease is a clinically evident disease of humans or animals that damages or injures the host so as to impair host function, and results from the presence and activity of one or more pathogenic microbial agents, including viruses, bacteria, fungi, protozoa, multicellular parasites, and aberrant proteins known as prions.
Also, it is noted that an infection however, is not synonymous with an infectious disease, as an infection may not cause clinical symptoms or impair host function.

Also, the recitation of HIV is <u>not</u> readily apparent in the specification as filed.
In turn, the support for "with the proviso that said infectious disease is <u>not</u> HIV" is <u>not</u> readily apparent in the specification as filed.

While negative limitations as set forth in the newly submitted "provisio" may be satisfactory in certain circumstances,
there must be written support for the negative limitation in the application as filed.
Applicant's amendment filed 02/02/2007, does <u>not</u> appear to provide sufficient written support for HIV and in turn, does <u>not</u> appear to provide sufficient written support for the proviso as well.

Therefore, the examiner maintains that the filing date of the instant claims is deemed to be the filing date of instant USSN 10/643,384, filed 8/19/2003.

The following is reiterated for applicant's convenience.

For example, it appears that the only support for the written description of "methods of treating infection in a patient having an infection" is the original claims of the instant application and not the instant specification, nor in the priority documents relied upon.

While the priority documents and the instant specification do disclose "the antigen may be one that already exists within the patient, such as a tumor antigen, or a bacterial or viral antigen" (e.g. see Summary of the Invention) or "flt3-L may be administered as a vaccine adjuvant … for immunization purposes to enhance an immune response against tumor, viral or bacterial antigens" (e.g., see page 14, paragraph 2 of the instant specification),

Neither the instant specification nor the previous priority documents provide a sufficient written description for the broader genus of "treating an infection", broadly encompassed by the instant claims.

For example the reliance upon bacterial and viral antigens existing in patients or vaccines does not support broadening the disclosure of the priority documents to "treating infections", broadly encompassed by the instant claims.
Also, see MPEP 2163.05.

Again, if applicant desires priority prior to 8/19/2003 for the instant claims, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Therefore, this application repeats a substantial portion of prior USSN 10/241,927, filed 9/11/2002 and adds and claims additional disclosure not presented in the prior application, as indicated above. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Therefore, applicant should amend the first line of the specification to indicate the status of the instant application as a continuation-in-part.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

4. Applicant's arguments and the examiner's rebuttal concerning priority and sufficient written description of the claimed methods in the application (and, in turn, the specification) have been addressed above in the Section on priority.

As noted above, the claims now also recite "with the proviso that said infectious disease is not HIV".

Also, the recitation of HIV is not readily apparent in the specification as filed.
In turn, the support for "with the proviso that said infectious disease is not HIV" is not readily apparent in the specification as filed.

While negative limitations as set forth in the newly submitted "provisio" may be satisfactory in certain circumstances,
there must be written support for the negative limitation in the application as filed.
Applicant's amendment filed 02/02/2007, does not appear to provide sufficient written support for HIV and in turn, does not appear to provide sufficient written support for the proviso as well.

Therefore, the examiner maintains that the filing date of the instant claims is deemed to be the filing date of instant USSN 10/643,384, filed 8/19/2003.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l).
Correction of the following is required:

As indicated above with respect to priority and upon a review of the instant specification, it does not appear that the instant specification provides for antecedent basis for the recitation of "methods of treating infection in a patient having an infection" other than in the original claims of the instant application.

Again, this "limitation" including the newly submitted "proviso" is not readily apparent in the instant specification, nor in the priority documents relied upon.

Applicant should note the New Matter rejection set forth herein due to the submission of the "proviso".

Alternatively, applicant is invited to identify the written support for instant claims in the specification as filed (and as well as any USSN document relied upon for priority).

5. *This is a New Grounds of Rejection under 35 USC, 112, first paragraph, Written Description / New Matter.*

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed: "with the proviso that said infectious disease is not HIV".

Applicant's amendment, filed 02/07/2007, does not appear to provide sufficient direction to this "negative proviso" in the specification as filed.

Applicant's arguments, filed 02/07/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

The recitation of HIV is not readily apparent in the specification as filed.

In turn, the support for "with the proviso that said infectious disease is not HIV" is not readily apparent in the specification as filed.

While negative limitations as set forth in the newly submitted "negative proviso" may be satisfactory in certain circumstances,

there must be written support for the negative limitation in the application as filed.

Applicant's amendment filed 02/02/2007, does not appear to provide sufficient written support for HIV and in turn, does not appear to provide sufficient written support for the proviso as well.

The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide blaze marks, nor direction for the instant methods encompassing the above-mentioned "negatitve proviso", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "negative proviso" indicated above.

See MPEP 714.02 and 2163.06

6. Claims 1-23 are rejected under 35 U.S.C § 102(e) as being anticipated McKenna et al. (US 2004/0022760) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention).

Applicant's arguments, filed 02/07/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

McKenna et al. teach the use of Flt3-ligand (e.g., see paragraphs [0054] – [0068]) in immunization protocols (e.g., see Therapeutic applications in paragraphs [0089] – [0159]), including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see paragraphs [0078] –[0085], including Table 1 on pages 10-11 and paragraphs [0127] – [0129]) as well as known pharmaceutical compositions (e.g. see paragraphs [0085], [0092], [[0096] - [0120]) and modes of administration (e.g., see paragraphs [0121] –[0126] recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

7. Claims 1-23 are rejected under 35 U.S.C § 102(e) as being anticipated Rosenthal et al. (U.S. Patent No. 6,875,441) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention).

Applicant's arguments, filed 02/07/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Rosenthal et al. teach the use of Flt3-ligand (e.g., see Background of the Invention, column 7, paragraph 3 and Examples) in immunization protocols (e.g., see column 11, paragraph 6) including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see column 11, paragraphs 6-7) as well as known pharmaceutical compositions and modes of administration (e.g., see columns 12-13) recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

8. Claims 1-9, 11-15 and 17-23 are rejected under 35 U.S.C § 102(b) as being anticipated Lyman et al. (U.S. Patent No. 5,554,512) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention).

Applicant's arguments, filed 02/07/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir. 1997).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Applicant's arguments, filed 02/07/2007, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Lyman et al. teach the use of Flt3-ligand (e.g., see columns 4-17 and Examples) [0068]) as well as known pharmaceutical compositions and modes of administration (e.g., see column 18, paragraphs 3-4) that can be use in methods to stimulate T cell proliferation as well hemopoietic cells in treating patients with HIV (e.g. see column 7, paragraph 3) encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

It is noted that even if applicant is able to obtain the earliest priority document relied upon, this reference would still stand as prior art under 35 USC 102(e).

9. The previous provisional rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of copending USSN 10/397,687 has been rendered moot,
given the abandonment of USSN 10/397,687.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 30, 2007

Phillip Gambel